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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/155,676	01/04/1999	DAVID WALLACH	WALLACH=21	8997

1444 7590 04/17/2007  
BROWDY AND NEIMARK, P.L.L.C.  
624 NINTH STREET, NW  
SUITE 300  
WASHINGTON, DC 20001-5303

EXAMINER
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EPPS FORD, JANET L

ART UNIT	PAPER NUMBER
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1633

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/17/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/155,676	<b>Applicant(s)</b> WALLACH ET AL.	
	<b>Examiner</b> Janet L. Epps-Ford	<b>Art Unit</b> 1633	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 March 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13-16, 20-22, 43, 44, 46, 47, 49, 50, 53-60, 62-71, 73-75 and 77-79 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 47, 62-64, 70 and 71 is/are allowed.
- 6) ☒ Claim(s) 13-16, 20-22, 43, 44, 49, 54, 55, 59, 60 and 69 is/are rejected.
- 7) ☒ Claim(s) 46, 50, 53, 56-58, 65-68, 73-75 and 77-79 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 13-16, 20-22, 43-44, 46-47, 49-50, 53-60, 62-71, 73-75, 77-79 are presently pending.

#### ***Claim Rejections - 35 USC § 112-Description***

4. Claims 13-16, 20-22, 43-44, 49, 54-55, 59-60, and 69 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the Official Action mailed 9-05-02, and those set forth in the Official Action mailed 6-27-03.

Applicant's arguments filed 3-21-07 have been fully considered but are not persuasive. Applicants traverse the instant rejection by means of amending the claims. Specifically Applicants argue:

5. "[W]hile applicants continue to disagree with the examiner's position about the written description support for fragments, nevertheless, the claims have now been *amended to delete all reference to fragments*, so as to place the case into condition for allowance. This amendment is explicitly made without prejudice toward the continuation

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of prosecution of claims directed to such fragments in a continuing application. Furthermore, in view of the examiner's comments about the genus of "activities," the claims have been amended to recite only the activity of binding to TRAF2. The claims no longer recite the additional activity of "and either exhibits or increases the activity of NF-KB." Thus, the examiner's new rejection of this term as being nebulous has been obviated by its deletion. Binding to TRAF2 is a specific and substantial utility and is not nebulous."

6. Contrary to Applicant's assertions, the instant claims still encompass "fragment language", in particular claim 55 (iv) recites a DNA sequence capable of hybridization to a sequence of (i)-(iii) and which encodes a polypeptide that binds to TRAF2. It is noted that the DNA sequence need only hybridize to "a sequence" of (i)-(iii)," there is no requirement that DNA sequence comprise the full length sequence of the sequences recited in claim 55(i)-(iii). Moreover the DNA sequence of claims 55(iv) need only encode a polypeptide that binds to TRAF2, there is no requirement that this DNA encode a full length NIK protein, the scope therefore encompasses fragments of the polypeptides of the instant invention.

7. Additionally, claim 69 recites an isolated polypeptide that binds to TRAF2, said polypeptide: "(a) comprising....an amino acid sequence encoded by the nucleotide sequence of SEQ ID NO: 6." The phrase "*an amino acid sequence*" as compared to the phrase "*the amino acid sequence*" is not limited to one particular polypeptide that is encoded by SEQ ID NO: 6. The scope of the phrase "*an amino acid sequence*" broadly

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encompasses fragments of the polypeptide encoded by SEQ ID NO: 6, wherein said fragments must comprise a sequence that binds to TRAF2.

The specification as filed at paragraphs [0206]-[0207] teach only two forms of the NIK protein that is capable of binding to TRAF2. Specifically, the full length NIK protein was disclosed as binding to both the C-terminal and N-terminal regions of the TRAF2 protein, and the partial NIK clone (NIK 624-947) binds only to the C-terminal region of the TRAF2 protein. There are no other examples in the specification as filed, which describe the amino acid structure of partial clones of NIK that function to bind TRAF2.

Applicant's arguments do not take the place of evidence that Applicant's were in possession of the full scope of the claimed invention at the time of filing of the instant application.

#### ***Status of Applicant Initiated Interference***

8. As stated in the reply filed 3-21-07, Applicants have withdrawn their request for the initiation of an interference over US Patents 5,843,721 and 5,844,073.

#### ***New Grounds of Rejection/Objection***

##### ***Claim Objection***

9. Claim 53 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 20. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

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10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

11. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

12. Claim 60 is rejected under 35 U.S.C. 102(e) as being anticipated by McElroy et al. (US Patent No. 5,641,876), as evidence by Branch.

Instant claim 60 recites the following:

An anti-sense oligonucleotide consisting of a sequence complementary to at least a portion of the mRNA encoding a TRAF2-binding polypeptide comprising the amino acid sequence of SEQ ID NO: 2, an amino acid sequence encoded by the nucleotide sequence of SEQ ID NO:3, or the amino acid sequence of SEQ ID NO:5, said anti-sense oligonucleotide being capable of effectively blocking the translation of said mRNA.

McElroy et al. discloses an oligonucleotide of 88 base pairs in length (SEQ ID NO: 19), wherein said oligonucleotide is 96% complementary to nucleotides 11-62 of SEQ ID NO: 1 of the instant application. This oligonucleotide consists of a sequence complementary to at least a portion of mRNA encoding a TRAF-2 binding polypeptide comprising the amino acid sequence of SEQ ID NO: 2 according to the present

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invention. SEQ ID NO: 21 of McElroy et al. is also 96 % complementary to nucleotides 11-62 of SEQ ID NO: 1 of the instant application. Although the prior art does not teach that the disclosed oligonucleotides would function as an antisense molecule to effectively block translation of the claimed mRNA encoding a TRAF2-binding polypeptide according to the present invention, absent evidence to contrary since the oligonucleotide of McElroy et al. has significant complementarity to SEQ ID NO: 1, it would also function to effectively block translation of the mRNA produced from this sequence. According to Branch, it has been demonstrated that a DNA-RNA hybrid of only 7 base pairs can lead to cleavage by RNaseH. Therefore, due to the significant level of complementarity between the oligonucleotides of McElroy et al. and SEQ ID NO: 1 of the instant application, the ordinary skilled artisan would have expected that the oligonucleotide of McElroy et al. would potentially form at least a 7 base pair duplex with the mRNA of SEQ ID NO: 1, and therefore illicit cleavage by RNase H, and thereby effectively block translation of the mRNA.

The burden of establishing whether the prior art oligonucleotide has the further function of inhibiting gene expression under generally any assay conditions falls to Applicant. See MPEP 2112.01, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing

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that they are not.” In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

***Conclusion***

13. Claims 47, 62-64, and 70-71 are allowable.

14. Claims 46, 50, 53, 56-58, 65-68, 73-75, and 77-79 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

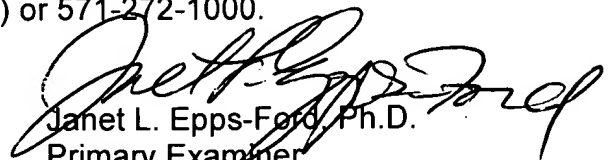


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15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Janet L. Epps-Ford, Ph.D.  
Primary Examiner  
Art Unit 1633

JLE